

Remarks

Claims 15-20 are currently pending in the application. Claim 15 has been amended to more particularly point out that an outermost edge of the annular continuous sealing zone forms a plane with, is directly adjacent to and is in continuous abutting contact with an entire outermost circumferential edge of the inert film. Currently amended claim 15 is at least supported by Figs. 9-12 and specification paragraphs [0012] and [0044].

The specification has been amended to include recitations to the amended claim language. Support for these amendments can be found in Figs. 9-12 and original specification paragraphs [0012], [0044] and [0045].

Accordingly, no new matter has been added and entry of the amendments is respectfully requested.

Objection to the Specification

The Examiner has objected to the specification because it has failed to provide proper antecedent basis for the claimed subject matter. Applicant has amended specification paragraphs [0012] and [0045] to provide proper antecedent basis for the claimed subject matter. Applicant respectfully submits that the specification is in full compliance with the requirements. Applicant respectfully requests that the objection to the specification be withdrawn.

Claim Rejections

The Examiner has rejected claims 15-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 2,895,773 (McConnaughey) in view of European Patent No. 0148426 (Pharma Gummi). The Examiner acknowledges that McConnaughey fails to disclose a piston section being enclosed in a cap-shaped inert film where the film comprises a fluorinated polymer film. The Examiner relies upon Pharma Gummi to teach a piston section of the piston stopper enclosed in a cap-shaped inert film comprising a fluorinated polymer film. The rejection of amended claim 15, and claims 16-20 depending therefrom, is respectfully traversed.

Referring to Fig. 3, McConnaughey discloses a piston cap 310 for a plunger head 320 which is placed inside a cylindrical barrel 330. The piston cap 310 is comprised of external annular ridges 302a, 302b and a free floating ring 302c. Further, a first intermediate groove 303a

is located between the first external annular ridge 302a and the free floating ring 302c and a second intermediate groove 303b is located between the second external annular ridge 302b and the free floating ring 302c.

Referring to Fig. 18, Pharma Gummi discloses a piston 33 for use in a pharmaceutical syringe. The piston 33 is comprised of three radially protruding sealing bulges 34, 35, 36. The first sealing bulge 34 is sheathed with a fluorinated polymer film 8 which is undetachably connected to the rubber-elastic material of the piston 33.

Assuming, *arguendo*, that McConnaughey is properly combinable with Pharma Gummi, the proposed combination would fail to disclose Applicant's invention as claimed in amended claim 15.

Claim 15, as amended, recites, *inter alia*,

the sealing section (10) has on its outer circumference an annular continuous sealing zone (13), and wherein an outermost circumferential edge of the continuous sealing zone (13) forms a plane with, is directly adjacent to and is in continuous abutting contact with an entire outermost circumferential edge of the inert film (9').

McConnaughey fails to disclose that an outermost circumferential edge of the continuous sealing zone forms a plane with, is directly adjacent to and in is continuous abutting contact with an entire outermost circumferential edge of the inert film or piston section. In the Office Action, the Examiner defined the first external annular ridge 302a as the piston section and both the free floating ring 302c and the first intermediate groove 303a as the annular continuous sealing zone. An outermost circumferential edge of both the free floating ring 302c and the first intermediate groove 303a does not form a plane with an entire outermost circumferential edge of the first external annular ridge 302a while being directly adjacent to and in continuous abutting contact with and outermost circumferential edge of the annular ridge 302a.

Conversely, an outermost circumferential edge of both the free floating ring 302c and the first intermediate groove 303a disclosed by McConnaughey does not form a plane with and is not flat or level with the first intermediate groove 303a. As described in McConnaughey, the first intermediate groove 303a is located between the first external annular ridge 302a and the free floating ring 302c. Therefore, the groove 303a between the ridge 302a and the ring 302c

prevents an outermost circumferential edge of this structure from forming a plane with, being directly adjacent to and being in continuous abutting contact with an entire outermost circumferential edge of the inert film or piston section.

Pharma Gummi does not make up for this deficiency. Pharma Gummi fails to teach an outermost circumferential edge of the continuous sealing zone forming a plane with, being directly adjacent to and being in continuous abutting contact with an entire outermost circumferential edge of the inert film. Assuming, *arguendo*, that the second sealing bulge 35 taught by Pharma Gummi is an annular continuous sealing zone 13 as disclosed in the instant application, the second sealing bulge 35 is separated from the inert film by a groove 43. Therefore, due to this separation, an outermost circumferential edge of the second sealing bulge 35 does not form a plane with, is not directly adjacent to and is not in continuous abutting contact with an entire outermost circumferential edge of the inert film.

Since Pharma Gummi does not teach that an outermost circumferential edge of the annular continuous sealing zone forms a plane with, is directly adjacent to and is in continuous abutting contact with an entire outermost circumferential edge of an inert film, it could not have been obvious to one of ordinary skill in the art to create such a structure in McConnaughey. As described in paragraph [0007] of the instant application, Applicant notes that the first sealing bulge 34 sheathed with the inert film 8, as taught by Pharma Gummi, is a relatively poor seal to prevent medication from seeping into the groove 43 between the first and second sealing bulges 34, 35. Combining this teaching of Pharma Gummi with the structure disclosed by McConnaughey does not accomplish the same result as that of the instant application, namely reliably preventing contact between the contents in the syringe and the uncoated sealing section.

Applicant's invention, as recited in amended claim 15, provides that an outermost circumferential edge of the annular continuous sealing zone (13) forms a plane with, is directly adjacent to and is in continuous abutting contact with an entire outermost circumferential edge of an inert film, thus avoiding that medication can seep into groove 12. Even if the first external annular ridge 302a of McConnaughey is enclosed by the inert film 8 of Pharma Gummi, as proposed by the Examiner, the resulting combination would resemble Fig. 18 of Pharma Gummi and would not create an outermost circumferential edge of the annular continuous sealing zone

forming a plane with, being directly adjacent to and being in continuous abutting contact with an entire outermost circumferential edge of an inert film.

McConnaughey in view of Pharma Gummi does not disclose each and every element of amended claim 15. Claims 16-20 are dependent on claim 15 and are therefore patentable over McConnaughey in view of Pharma Gummi for at least the same reasons discussed above.

Applicant respectfully submits that claim 15, and claims 16-20 depending therefrom, are not unpatentable over McConnaughey in view of Pharma Gummi, and requests that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn

CONCLUSION

In view of the foregoing Amendment and remarks, Applicant respectfully submits that the present application, including claims 15-20, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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